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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,442	02/15/2002	Partha Neogi	P 0290459 08948-010001	1127

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EXAMINER

REYES, HECTOR M

ART UNIT PAPER NUMBER

1625

DATE MAILED: 08/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/075,442

Applicant(s)

NEOGI ET AL.

Examiner

Hector M Reyes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25 to 30; 47 to 50 and 67 to 70 is/are pending in the application.
- 4a) Of the above claim(s) 28-30, 49, 70, 50 and 69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 25 to 27; 47, 48, 67 and 68 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ . 6) ☐ Other: _____

DETAILED ACTION**Paper Entry**

Examiner acknowledges Applicant's Requests for Extension of Time filed on July 12, 2002 as Paper no. 3 and Applicant's Response to the Restriction Requirement filed on July 24 2002 as paper no. 4. In such paper, Applicants elected without traverse Group 1, directed to claims 25-27, 47-48 and 67 to 68, which is hereby acknowledged by the examiner. On page 3 of the Election/ Restriction Request, the Examiner required from Applicants under 35 USC 121 to elect a single disclosed specie for prosecution on the merits. Applicant's election of "species of X =ether" is not found responsive because such election represent a sub-genus and not a single specie of the disclosed species. Nevertheless for practical purposes, the Examiner directs the prosecution of the instant Application to any specie within the elected subgenus: species within the subgenus having X as oxygen in the general chemical formula II.

Specification Objections

The disclosure is objected to because of the following informalities: The text of the specification is not clear, some letters are faded, specially the first letters near the left margins of the page; some tables have faded lines (see page 2), some apparent coma sings are faded to the extend that are more likely to be apparent period sings. Scheme I, as disclosed in the Preliminary Amendment is also objected to because the letter Scheme as a double S and because overlap of rings in the first structure having three rings.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 25 to 27; 47, 48 and 67 to 68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In Claim 25, Applicants claim an extensive list of compounds, having the general formula II. The method of preparation of such compounds, however, is not described anywhere in the specification. Regarding such preparation, in page 9 of the specifications it is said "A specific method for the synthesis of a representative number of compounds of the formula I is shown below in Scheme IA. *Compounds of the formula II where made starting from the second step showing in Scheme I with the appropriate starting materials.* Such limited sentence in reference to a general Scheme is insufficient to describe a proper preparation of the claimed compounds in such a way that enable one skill in the art to make such extensive number of compounds without undue experimentation. The factors to considering in determining the required undue experimentation are, among others:

- The breadth of the claim
- The nature of the invention
- The state of the art

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- The level of one of ordinary skill
- The level of predictability in the art
- The amount of direction provided by the inventor
- The existence of working examples
- The quantity of experimentation needed to make or use the invention based on the content of the disclosure see discussion of *In re Wands* 858 F2d 731, 737, 8 USPQ2d1400, MPEP 2164.01 and 2164.01(a).

In this particular case,

- Claim 25 embraced a quite extensive groups of compounds as can be deduced by the extensive groups that can satisfied the 10 variables moieties present in the said general formula;
- The specification lacks a disclosure of at least one working example describing the preparation of any of the compounds embraced by formula II
- In the organic synthesis art, the preparation of a given compound require to follow an specific sequence of steps and to control a variety of conditions in order to successfully prepared such compounds. Such reaction conditions are needed because it is unpredictable if a given starting material under a given and particular reactions conditions will eventually produce a wanted target. Conditions such as mixing order, initial temperature, pressure, time, etc should be at least define to certain and considerable extend, in such a way that a person skill in the art can reproduce the synthetic procedure without undue experimentation.

- In this particular case the only disclosure directed to the synthesis of the claimed compounds is a general reference to a general Scheme, without providing even one example of the required synthetic procedure for the preparation of specie within the broad claimed genus. Moreover, in the specification, page 1, first sentence, the novelty of such derivatives is disclosed, since is said, "the present application is directed to novel antidiabetic compounds. Therefore, there should not be any disclosed method in the art that can allow a person skilled in the art to prepare such derivatives.
- In the absence of such procedure, extensive experimentation directed to find the proper reactions conditions in the preparation of any compound embraced in such extensive list of claimed is required. Moreover, the finding of proper conditions in the preparation of the most simple species does not warranty that the same conditions could be used in the preparation of other more complicated structures, for example, in compounds having multiple substituents with a variety of functionalities which may required protection and de-protection or specific and particular reactions conditions. The preparation of pharmaceuticals preparations or any method of use the claimed compounds are other aspects of the instant invention. However, if the claimed derivatives cannot be synthesized, then such aspects of the instant invention are affected because without the compounds, their method of use or the preparation of compositions comprising the same cannot be achieved.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear which of the periods found in claim 1 finalized the description of the claimed invention. There is a total of four periods on the claim: after the letter H and after the word alkylcarboxylamino in the B and B' variable definition, after the word cyano in the R groups definition and after the SO₂ group in the X group definition. In claim 26, there is a total of two periods: after the word cyano and after the SO₂ group in the X definition. Please see section 608.01(m) of the MPEP, wherein had been point out that "Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations".

Claims 25, 26 27, 47, 48, 67 and 68 are unclear. While in such claim, the variables At, Bx, Cw, Au and By are defined as substituents on any position of the specific ring, the values of t, u, y, x and w are defined as 0 to 3. Therefore, such definition includes those compounds wherein the variables groups A, B and C or A' and B' are not present in the ring since the value of t, u, y, x and w can be zero. Hydrogen is included within the definition of A, A' B, B' and C groups and therefore excluded as a possibility when all the variables t, u, y, x and w are 0. In such instances, it is not indicated which substituents are found in any of the rings and therefore in such case the definition of the

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claimed compounds is indefinite. Definition of the substituents on the ring when t, u, y, x and w are zero is required in order to clarify both claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25, 27 47, 48, 67 and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by Kummer et al, US patent 4,110,470.

Kummer discloses:

- a series of compounds having the general formula 1, as described in column 2, lines 24 to 62,
- its method of preparation as detailed on columns 3, 4, 5 and 6 and in the pertinent examples 1 to 9
- Pharmaceutical preparations comprising such derivatives as described in example 10 to 11,

Kummer also discloses that such derivatives are especially noteworthy for they lipid-controlling including their cholesterol-controlling properties, such as lowering the level of cholesterol and also of triglycerides in warm-blooded animals. These properties were confirmed in clinical work on patients suffering from diabetes and in other patients suffering other related diseases (see col. 14, lines 39 to 52).

CONCLUSION

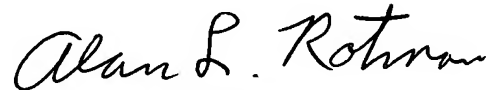
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hector M Reyes whose telephone number is (703) 605-1153. The examiner can normally be reached on M-F 9 to 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Allan Rotman can be reached on (703) 308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 or (for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

August 19, 2002

Héctor M. Reyes PhD. JD.



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